

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
DEY, L.P. and DEY, INC.,	:	
	:	
Defendant.	:	
<hr/>		: Civil Action No. 06-113-JJF
	:	: (CONSOLIDATED)
SEPRACOR INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
BARR LABORATORIES, INC.,	:	
	:	
Defendant.	:	
	:	

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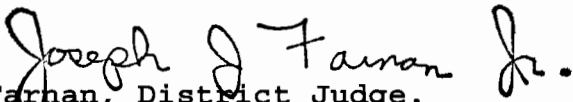
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**MEMORANDUM OPINION**

September 26, 2008  
Wilmington, Delaware

  
Farnan, District Judge.

Presently before the Court is a Motion to Strike Plaintiff's Claim For Willful Infringement, filed by Defendants Dey, L.P. and Dey, Inc. (collectively, "Dey") (D.I. 68.) For the reasons discussed, the Court will grant Dey's Motion To Strike Plaintiff's willfulness allegations. However, to the extent Dey's Motion implicates the striking of Plaintiff's exceptional case claim, the Court will deny the motion.

#### **BACKGROUND**

In response to Dey's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic levalbuterol hydrochloride solutions, Plaintiff Sepracor, Inc. ("Sepracor") brought this action, alleging infringement of U.S. Patent Nos. 5,362,755; 5,547,994; 5,760,090; 5,884,002; and 6,083,993. With its ANDA filing, Dey included a Paragraph IV certification stating that it believed Sepracor's patents to be either invalid or not infringed by Dey's levalbuterol hydrochloride solutions. In its Complaint, Sepracor alleged that this Paragraph IV certification was "devoid of an objective good faith basis in either the facts or the law." (D.I. 1, ¶ 25.) Seeking a judgment that Dey's infringement is willful, Sepracor further alleged in its Complaint that Dey's ANDA filing constituted "willful and deliberate" infringement. (D.I. 1, ¶ 26.) In an interrogatory, Dey requested the "factual and legal basis" for Sepracor's willfulness allegations. (D.I. 76 at 3.) Sepracor objected to the

interrogatory, stating that the parties were in negotiations to dismiss Sepracor's willfulness allegations. (Id.) Believing negotiations to be at a standstill, Dey brought the instant Motion, contending that Federal Circuit and district court precedent precludes a finding of willful infringement strictly on the basis of an ANDA filing.

#### **PARTIES' CONTENTIONS**

In support of its motion, Dey directs the Court to the Federal Circuit's opinion in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351-52 (Fed. Cir. 2004). There, the Federal Circuit held that "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination" because such a filing merely creates "an artificial act of infringement for purposes of establishing jurisdiction in the federal courts . . . ." Id. (emphasis in original); see also id. at 1350-51 ("[W]e now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)."). Sepracor further directs the Court to the Boehringer Ingelheim Intern. GMBH v. Barr Labs, Inc., No. 05-700, 2006 U.S. Dist. LEXIS 46835, at \*8 (D. Del. Jul. 6, 2006) decision from this District. In Boehringer, "no other basis exist[ed] for the assertion of willfulness besides the defendants' filing of ANDAs," so the Court, citing Glaxo, struck the plaintiff's willfulness allegations. See Boehringer, 2006 U.S. Dist. LEXIS 46835, at \*4,

\*8.

Sepracor acknowledges the recent authority holding that the mere filing of an ANDA cannot support a claim for willful infringement. (D.I. 74 at 2-4.) However, Sepracor contends that its willfulness pleadings "relate to Dey's 'willfulness' as it pertains to exceptional case under section 285." (Id. at 5; see also id. at 6 ("Sepracor's pleading of 'willfulness' for purposes of exceptional case puts Dey on more than sufficient notice in accordance with Rule 8(a).").) Though the Court is uncertain as to what Sepracor means when it places the word "willfulness" in quotes and refers to such things as "'willfulness' for purposes of exceptional case," Sepracor quite clearly contends that if the Court were to grant Dey's motion, it would, in addition to eliminating Sepracor's willfulness allegation, eliminate Sepracor's claim of exceptional case. (Id. at 6). Sepracor contends that it would be inappropriate for the Court to do this. Sepracor further argues that Dey's motion is untimely because it was not filed before responding to Sepracor's Complaint.

## **DISCUSSION**

### **I. Legal Standard**

Federal Rule of Civil Procedure 12(f) states, in relevant part, that "[a] court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "[T]he purpose of a

motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." McInerney v. Moyer Lumber and Hardware, Inc., 244 F. Supp. 2d 393, 402 (E.D. Pa. 2002). Motions to strike are generally disfavored and "usually will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties." Id.

## **II. Analysis**

Although the Federal Circuit was quite clear in Glaxo that the filing of an ANDA application or certification is only an artificial "act of infringement" that cannot support a claim for willful infringement, Glaxo, 379 F.3d at 1350-52, plaintiffs in Hatch-Waxman actions have continued to allege willfulness when the only alleged act of infringement was an ANDA filing. Following Glaxo, district courts - including those of this district - have repeatedly dismissed such allegations in a variety of procedural postures. See Janssen, L.P. v. Barr Labs., Inc., No. 07-1515, 2008 U.S. Dist. LEXIS 7965, at \*12-\*13 (D.N.J. Feb. 4, 2008); Forest Labs., Inc. v. Ivax Pharms., Inc., No. 03-891, 2007 U.S. Dist. LEXIS 18214, at \*8 (D. Del. Mar. 15, 2007); Boehringer, 2006 U.S. Dist. Lexis 46835, at \*8; Wyeth, Cardinal Health, Inc. v. Ranbaxy Labs., Ltd., 448 F. Supp. 2d 607, 612 (D.N.J. 2006); Item Dev. AB v. Sicor Inc., No. 05-336, 2006 U.S. Dist. LEXIS 15386, at \*7-\*8 (D. Del. Mar. 31, 2006); Aventis Pharma Deutschland GmbH v. Lupin Ltd., 409 F. Supp. 2d 722, 731 (E.D. Va. 2006); UCB Societe Anonyme

v. Mylan Labs., Inc., No. 04-cv-683, 2006 U.S. Dist. LEXIS 10854, at \*9 (N.D. Ga. Feb. 28, 2006); Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc., 355 F. Supp. 2d 586, 592-593 (D. Mass. 2005).

As in the above cases, Sepracor's willfulness allegations are based strictly on Dey's allegedly baseless ANDA filing, a point that Sepracor does not rebut in its briefing. Nor does Sepracor identify any facts or cases that would compel a departure from Glaxo or the persuasive district court authority that has followed in Glaxo's wake. Though Dey may have waited to file its Motion to Strike until after responding to Sepracor's Complaint, it would be inappropriate for the Court to allow Sepracor's willfulness allegations to proceed after the Federal Circuit and numerous district courts have confirmed that such allegations have no legal basis. Accordingly, the Court will strike Sepracor's allegations of willfulness.

Notwithstanding this determination, the Court notes that the above authority has also confirmed that, although the filing of an ANDA cannot support a finding of willfulness, a "myriad of factual circumstances may give rise to a finding that a case is exceptional . . . ." Glaxo, 376 F.3d at 1350. For instance, the Federal Circuit explained in Glaxo that "unjustified litigation and misconduct," such as "numerous baseless filings supporting ... fruitless and meritless arguments, both in [a] case at trial and in [an] ANDA certification," have always justified a finding of an exceptional case. Id. Consistent with Glaxo, courts in this

district, when striking willfulness allegations based on ANDA filings, have always permitted plaintiffs to continue pursuing an exceptional case claim. See Boehringer, 2006 U.S. Dist. LEXIS 46835, at \*8; Forest Labs., 2007 U.S. Dist. LEXIS 18214, at \*9-\*10; Item Dev. AB, 2006 U.S. Dist. LEXIS 15386, at \*7-\*8. Accordingly, the Court will tailor its Order to ensure that Sepracor's exceptional case claim remains intact.

The issues discussed above are implicated in the following paragraphs of Sepracor's complaint:

25. On information and belief, Dey, L.P.'s statement of the factual and legal basis for its opinion regarding the validity of the Sepracor Patents is devoid of an objective good faith basis in either the facts or the law.

26. On information and belief, in filing its ANDA No. 77-800 to obtain approval to engage in the commercial manufacture, use and/or sale of Dey's Levalbuterol Inhalation Solutions before the expiration of the Sepracor Patents, Dey, L.P.'s infringement of the Sepracor Patents is, has been and continues to be willful and deliberate.

....

WHEREFORE, Sepracor prays for judgement as follows:

....

(D) A judgment that Dey, L.P.'s and Dey, Inc's infringement of the Sepracor Patents was and is willful and that Sepracor is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

(D.I. 1, at ¶¶ 25-26, (D).) The only paragraph that pertains strictly to Sepracor's willfulness allegation is paragraph 26, which alleges that Dey's ANDA filing constitutes willful infringement. This paragraph will be stricken in its entirety. On the other hand, paragraph 25 merely alleges that Dey's ANDA filing

is baseless. As the Federal Circuit explained, such an allegation is pertinent to an exceptional case claim, see Glaxo, 376 F.3d at 1350, and will thus not be stricken. Paragraph (D) refers to both willful infringement "and" the award of attorneys' fees pursuant to 35 U.S.C. 285. Though willful infringement often supports a finding of exceptionality, the two issues are nonetheless distinct and willful infringement is not a prerequisite to exceptionality. See id. Accordingly, to the extent paragraph (D) prays for a judgment of willful infringement, it will be stricken. To the extent it prays for a judgment that the case is exceptional, it will be allowed to stand.

#### **CONCLUSION**

For the reasons discussed, the Court will grant Dey's motion as it pertains to Plaintiff's willfulness claim and deny Dey's motion to the extent it implicates the striking of Sepracor's exceptional case claim.

An appropriate Order will be entered.